



**CIRCULATORY SYSTEM DEVICES PANEL
AGENDA*****May 7, 2014***
Circulatory System Devices Panel
515i Classification Panel
Gaithersburg Hilton

On May 7, 2014, during session I, the committee will discuss and make recommendations regarding the classification of Membrane lung for long-term pulmonary support systems, one of the remaining preamendments Class III devices regulated under the 510(k) pathway. A membrane lung for long-term pulmonary support refers to the oxygenator component of an extracorporeal circuit used during long-term procedures, commonly referred to as an ECMO. An ECMO procedure provides assisted extracorporeal circulation and physiologic gas exchange of a patient's blood when an acute (reversible) condition prevents the patient's own body from providing the physiologic gas exchange needed to sustain life.

8:00 a.m.	Call to Order Introduction of Committee	John W. Hirshfeld, Jr., MD Chairperson
	Conflict of Interest Statement	Jamie Waterhouse, M.B.A. Designated Federal Officer
8:10 a.m.	Reclassification Presentation	
8:25 a.m.	Questions from Committee	
8:35 a.m.	FDA Presentation	
9:35 a.m.	Questions from Committee	
9:45 a.m.	Open Public Hearing	
10:15 a.m.	Questions to OPH Speakers	
10:25 a.m.	Break	
10:40 a.m.	Panel Deliberations	
11:20 a.m.	FDA Questions to the Panel	
12:30 p.m.	Adjournment	

*** Open Public Hearing** – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.